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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Dall'Acqua et al.	Confirmation No.:	2678
Serial No.:	10/020,354	Art Unit:	1644
Filed:	December 12, 2001	Examiner:	Belyavskyi, Michail A.
For:	MOLECULES WITH EXTENDED HALF-LIVES, COMPOSITIONS AND USES THEREOF	Attorney Docket No:	10271-027

PROVISIONAL ELECTION UNDER 37 C.F.R. § 1.143 WITH TRAVERSAL

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In response to the Restriction Requirement, mailed December 29, 2004, and in accordance with Rule 143 of the Rules of Practice, please consider the following remarks.

It is estimated that no fee is required for filing this response. In the event that a fee is required, please charge the required fee to Deposit Account No. 16-1150.

REMARKS

Claims 1-86 are pending in this application. The Examiner has required an election under 35 U.S.C. § 121 of one of the following groups:

I. Claims 4, 7-20, 58, 69 and 86, drawn to a modified IgG, a pharmaceutical composition and a kit comprising modified IgG, wherein the modification is an amino acid substitution, classified in Class 530, subclasses 387.1, 387.7 and 387.9; Class 424, subclass 130.1; and Class 435, subclass 810.

II. Claims 5, 7, 8, 20, 58, 69 and 86, drawn to a modified IgG, a pharmaceutical composition and a kit comprising modified IgG, wherein the modification is an amino acid deletion, classified in Class

530, subclasses 387.1, 387.7 and 387.9; Class 424, subclass 130.1; and Class 435, subclass 810.

III. Claims 6, 7, 8, 20, 58, 69 and 86, drawn to a modified IgG, a pharmaceutical composition and a kit comprising modified IgG, wherein modification is an amino acid insertion, classified in Class 530, subclasses 387.1, 387.7 and 387.9; Class 424, subclass 130.1; and Class 435, subclass 810.

IV. Claims 24, 27-39, 59 and 70, drawn to a fusion protein comprising a non-Ig polypeptide, a pharmaceutical composition and a kit comprising said fusion protein, wherein the modification is an amino acid substitution, classified in Class 530, subclasses 350 and 387.1; Class 424, subclass 134.1; and Class 435, subclass 810.

V. Claims 25, 27-29, 59 and 70, drawn to a fusion protein comprising a non-Ig polypeptide, a pharmaceutical composition and a kit comprising said fusion protein, wherein the modification is an amino acid deletion, classified in Class 530, subclasses 350 and 387.1; Class 424, subclass 134.1; and Class 435, subclass 810.

VI. Claims 26-29, 59 and 70, drawn to a fusion protein comprising a non-Ig polypeptide, a pharmaceutical composition and a kit comprising said fusion protein, wherein the modification is an amino acid insertion, classified in Class 530, subclasses 350 and 387.1; Class 424, subclass 134.1; and Class 435, subclass 810.

VII. Claims 43, 46-57, 60 and 71, drawn to a molecule comprising a modified IgG constant domain, a pharmaceutical composition and a kit comprising said molecule, wherein the modification is an amino acid substitution, Class 530, subclasses 350 and 387.1; Class 424, subclass 133.1; and Class 435, subclass 810.

VIII. Claims 44, 60 and 71, drawn to a molecule comprising a modified IgG constant domain, a pharmaceutical composition and a kit comprising said molecule, wherein the modification is an amino acid deletion, Class 530, subclasses 350 and 387.1; Class 424, subclass 133.1; and

Class 435, subclass 810.

IX. Claims 45, 60 and 71, drawn to a molecule comprising a modified IgG constant domain, a pharmaceutical composition and a kit comprising said molecule, wherein the modification is an amino acid insertion, Class 530, subclasses 350 and 387.1; Class 424, subclass 133.1; and Class 435, subclass 810.

X. Claims 61-62, 72-77 and 79-84, drawn to a method of treating or preventing a disease or disorder and a method of vaccinating a subject, comprising administering to a subject in need a modified human or humanized IgG, classified in Class 530, subclasses 387.1 and 387.3; and Class 424, subclass 130.1.

XI. Claims 63 and 78, drawn to a method of treating a disease or disorder and a method of vaccinating a subject, comprising administering to a subject, comprising administering to a subject in need a fusion protein comprising a non-IgG polypeptide, classified in Class 530, subclasses 387.1 and 387.3; and Class 424, subclasses 130.1 and 192.1.

XII. Claim 64, drawn to a method of treating a disease or disorder, comprising administering to a patient in need a molecule comprising a modified IgG constant region, classified in Class 530, subclasses 387.1 and 387.3; and Class 424, subclasses 130.1 and 192.1.

XIII. Claims 65 and 67, drawn to a nucleic acid comprising a nucleotide sequence encoding the modified IgG constant domain and a host cell comprising said nucleic acid, classified in Class 536, subclass 23.5; and Class 435, subclasses 69.1, 455 and 325.

XIV. Claims 66 and 68, drawn to a nucleic acid comprising a nucleotide sequence encoding a fusion protein comprising a non-IgG polypeptide and a host cell comprising said nucleic acid, classified Class 536, subclass 23.5; and Class 435, subclasses 69.1, 455 and 325.

XV. Claim 85, drawn to a method of *in vivo* diagnosis in a subject, comprising administering to a subject an effective amount of the modified human or humanized IgG, classified in Class 530, subclasses

387.1 and 387.3; and Class 424, subclass 130.1.

The Examiner contends that the inventions of Groups I-XV are distinct from each other. Applicants respectfully traverse the Restriction Requirement and respectfully assert that the subject matter of Groups I-IX are so intertwined that a single search would identify any relevant art pertaining to an IgG constant domain comprising one or more amino acid modifications, regardless of whether the modified IgG constant domain is a part of a modified IgG, covalently linked a non-IgG-polypeptide, or covalently linked to a non-protein agent. Thus, contrary to the Examiner's contention, Applicants assert that to search and examine a modified IgG comprising a modified IgG constant domain, a fusion protein comprising a modified IgG constant domain covalently linked to a non-IgG polypeptide, and a molecule comprising a non-protein agent covalently linked to a modified IgG constant domain would not be a serious burden on the Examiner. The M.P.E.P. § 803 (Eighth Edition, Rev. 1, Feb. 2003) states:

> If the search and examination of an application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, in view of M.P.E.P. § 803, all of the claims of Groups I-IX should be searched and examined in the subject application. Accordingly, Applicants respectfully request that the Restriction Requirement Under 35 U.S.C. § 121 be modified such that claims 1-60, 69-71 and 86 are examined in one application.

At minimum, Applicants respectfully assert that Groups I-III should be examined together since the subject matter of Groups I-III are so intertwined that a single search would identify any relevant art pertaining to a modified IgG comprising an IgG constant domain comprising one or more amino acid modifications, regardless of whether the amino acid modification is a substitution, deletion or insertion. Thus, Applicants assert that to search and examine a modified IgG comprising a modified IgG constant domain would not be a serious burden on the Examiner. Accordingly, Applicants respectfully request that, at a minimum, the Restriction Requirement Under 35 U.S.C. § 121 be modified such that claims 1-20, 58, 69 and 86 are examined in one application

In order to be fully responsive, however, Applicants hereby elect to prosecute the claims of Group I, claims 4, 7-20, 58, 69 and 86, drawn to a modified IgG, pharmaceutical composition and a kit comprising modified IgG, with traverse, without

prejudice to Applicants' right to pursue the non-elected subject matter in related applications.

In addition to the election of one of Groups I-XV, the Examiner has required an election under 35 U.S.C. § 121 of one of the following antibody sequences: SYNAGIS®, AFFF, p12f2, p12f4, p11d4, Ale109, A12a6, A13c4, A17d4, A4B4, A8C7, 1X-493L1FR, H3-3F4, M3H9, Y10H6, DG, AFFF(1), 6H8, L1-7E5, L215B10, A13A11, A1H5, A4B4(1), A4B4L1FR-S28R, or A4B4-F52S. Applicants respectfully assert that a single search would identify any relevant art pertaining to a modified IgG comprising a modified IgG constant domain, regardless of the sequence of the variable heavy and variable light domains. Thus, contrary to the Examiner's contention, Applicants assert that to search and examine the subject matter of the antibody sequences together would not be a serious burden on the Examiner.

At a minimum, the requirement to elect a particular antibody sequence should be modified to a species election. Pursuant to M.P.E.P. § 806.04(d), claims 1-3 are generic claims which generically recite a modified IgG comprising a modified IgG constant domain. Under 37 C.F.R. § 1.146,

> [i]n the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable.

Thus, under the Rules of Practice, a species election, not further restriction is, at most, the appropriate action in this matter. Accordingly, Applicants respectfully request that the further Restriction Requirement under 35 U.S.C. § 121 of Group I be withdrawn or modified such that all of the antibody sequences recited in claims 19 and 20 are examined in one application, or at a minimum, that the further Restriction of Group I be modified to be a species election.

In order to be fully responsive, however, Applicants hereby elect to prosecute the antibody sequence of A4B4L1FR-S28R, without prejudice to Applicants' right to pursue the non-elected subject matter in related applications.

Further, the Examiner has required that Applicants elect a specific amino acid position and a specific substitution of the amino acid as species. In response, Applicants hereby elect to prosecute amino acid position 252 and tyrosine as the amino acid substitution,

without prejudice to Applicants' right to pursue the non-elected subject matter in related applications. Accordingly, in response to the Restriction Requirement and species elections, Applicants elect to prosecute claims 2, 3, 4, 7, 8, 10-12, 14, 15, 16, 18, 20, 58, 69 and 86.

Entry of the remarks made herein is respectfully requested. The Examiner is invited to contact the undersigned with any questions concerning the foregoing.

Respectfully submitted,

Date: January 29, 2004

Anthony M. Insogna 35,203
Anthony M Insogna (Reg. No.)

JONES DAY
222 East 41st Street
New York, New York 10017
(212) 790-9090

By: Jennifer J. Chhedo
Reg No. 46,617